

NIH issues genomic data sharing policy

The US National Institutes of Health (NIH)'s new data sharing policy, issued in August, hopes to speed the translation of genomic data into knowledge, products and procedures that improve health while protecting the privacy of research participants. The policy will apply to all NIH-funded, large-scale human and non-human projects that generate genomic data beginning with funding applications submitted by January 25, 2015. The GDS policy traces its roots to the Human Genome Project completed in 2003, which required rapid and broad data release. It replaces the previous Genome-Wide Association Studies (GWAS) data sharing policy, issued in 2007.

Vertex buries Incivek

Boston-based Vertex will discontinue sales of its hepatitis C virus treatment Incivek (telaprevir) barely three years since its approval in May 2011 (*Nat. Biotechnol.* **29**, 553, 2011). Incivek was one of the first antiviral treatments to double cure rates compared to standard treatment. It was approved for use in combination with pegylated interferon alpha and ribavirin to treat HCV genotype 1. But its dominance didn't last. The launch of the first all-oral, interferon-free regimen, active against all genotypes, Gilead's Sovaldi (sofosbuvir), in 2013 (*Nat. Biotechnol.* **32**, 3–5, 2014), quickly eroded Incivek's market share.

Exelixis slashes 70% of staff

Exelixis announced in September that it will cut 160 jobs after disappointing results for its lead drug Cometriq (cabozantinib) in prostate cancer. Cometriq is already approved to treat metastatic medullary thyroid cancer. But in a phase 3 comparison study of Cometriq, in men with castration-resistant prostate cancer, the small molecule failed to show a significant increase in overall survival compared with prednisone. Cometriq inhibits multiple tyrosine kinases including MET, VEGFRs and RET.

“We're not trying to create some characteristic that makes this person a stronger person or [someone who] will have blonde hair. We're trying to prevent disease and I think that is the only justification for doing this.” Doug Turnbull, from the University of Newcastle, UK, commenting on cytoplasmic transfer technique that he helped popularize in Europe. Some object to it on the grounds that it amounts to germ-line engineering. (*BBC News Magazine*, 31 August 2014)

“This is a big leap into the unknown for AbbVie. Google is used to leaping into the unknown but AbbVie is not.” Aubrey de Grey, CSO at SENS Research Foundation, comments on the \$1.5-billion partnership between AbbVie and Calico, Google's answer to aging. (*The Wall Street Journal*, 4 September 2014)

iPad, video-based technologies, adoption so far has been slow. For new companies braving the market, “The biggest strategic challenge here is focus,” says Arthur Hiller, chief business officer at Geppetto Avatars, a Mequon, Wisconsin-based startup, which aims to improve patient management and patient monitoring through the use of digital avatars powered by artificial intelligence. “The reality is we could do a thousand different things,” he says. Geppetto has developed a platform that integrates myriad technologies, including natural language processing, facial recognition, voice-to-text recognition and biometric data analysis, as well as insights from social psychology and behavioral science, into a ‘digital doctor’, which can interact with patients through ordinary speech and video. Two beta customers are already using the technology in undisclosed settings, and a first commercial version is due to ship this fall.

Such digital information could also be exploited for drug development. In difficult-to-diagnose degenerative conditions, such as Parkinson's disease or Alzheimer's disease, the Geppetto's face-recognition technology might monitor speech patterns or microfacial tremors. Although the company has not yet initiated such studies, “We have the potential to establish clinical endpoints that never existed before,” says Hiller.

Intel and the Michael J. Fox Foundation are testing smartwatches to follow symptom progression in patients with Parkinson's disease. The Intel Basis smartwatches and a specially developed app track body movements, rhythms and function, to produce information that could aid understanding of the disease and inform drug development. Other trials in patients with Parkinson's disease are testing whether Google Glass can help them retain their independence for longer. The device reminds people to take their medicine and attend medical appointments, and provides discreet prompts to speak louder and swallow.

Beyond tracking and monitoring, devices could be therapeutic. Adam Gazzaley, founding director of the Neuroscience Imaging Center at the University of California, San Francisco, and colleagues are testing whether a three-dimensional training video game, called NeuroRacer, can improve multitasking performance in older adults—assessed by their performance in playing the game—compared with two different control groups. “We were pretty excited by the strength of the signal we saw even though it was a very small population,” says Gazzaley, who reported the results last year. The performance improvements

lasted at least six months and also translated to improvements in working memory and sustained attention, which were assessed using different tests (*Nature* **501**, 97–101, 2013). “One of the biggest challenges is developing approaches that strengthen not only the individual ability to do that task but that also have a more generalized impact,” he says. Gazzaley is a cofounder of Akili Interactive Labs, a Boston-based company, which is developing a commercial version of the game. Shire, of Dublin (soon to become part of AbbVie, of North Chicago, Illinois), is an investor and is collaborating with the company on a clinical trial in 80 children with attention deficit hyperactivity disorder. Pfizer is assessing its potential as a diagnostic aid in Alzheimer's disease. “Pfizer's interest is, can game play over time be used as a more sensitive marker of cognitive ability than we have achieved with more standard neuropsychological testing?” says Gazzaley.

The end goal is to help the brain “train its way out” of a problem, to use gaming to harness the innate plasticity of the human brain. But contrary to Gazzaley's finding, other studies claim to have found no transfer effects from brain training programs (*PLOS One* **8**, e59982, 2013; *Nature* **465**, 775–778, 2010). Michael Merzenich, professor emeritus at the University of California, San Francisco, and cofounder of Posit Science, a brain training firm, also based in San Francisco, is critical of their findings. “It's not so easy to create a study that corrects a brain that's complexly distorted,” he says. “Most people operating in this realm are not neurologically informed.” But Posit and a sister firm, Brain Plasticity, also have several trials of cognitive training programs ongoing, in military veterans with traumatic brain injury and in schizophrenia patients, for example. “I consider this is going to be the dominant therapeutic approach in the not-too-distant future,” says Merzenich.

The field is still waiting on what Merzenich calls a “linchpin moment.” The pharma industry's present level of engagement has yet to move beyond the experimental stage. The digital health sector has yet to reach that point when clinical—or market—validation aligns with a sustainable business model. In the long run, the companies that succeed in this space may be those that best integrate the brash, consumer-oriented culture of the technology sector with the more conservative, regulation-bound ethos of drug and device development. No FDA label has ever included the word ‘awesome’.

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